

840 Coronado Drive,
Glendale, CA 91206

March 7, 2000 5025 '00 MAR 21 A9:47

Ms. Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Henney:

I am informed that interested parties are seeking to induce the FDA to take away individuals rights to waive medical exams or hearing tests when purchasing hearing aids. Having had considerable personal experience, and having studied the subject of hearing loss and attempts to compensate for it, and having had the medical and audiology exams, as well as having purchased aids via both mail order companies, and through the standard audiologist/ name brand route, I believe my comments have validity:

First - While it might be advisable for a person to have a medical exam, the unfortunate truth is that for the preponderance of hearing loss sufferers, there is little or nothing that can be done medically. Why should we require that a person have a medical exam for this defect when we do not do so for other physical problems which potentially can be far more serious?

Second - Taking the "high road" toward the purchasing of hearing aids, i.e. the medical exam, in some cases including X-Rays or MRI's, audiology tests, followed by the purchase of top of the line aids can be very expensive, but also has significant advantages and benefits for those able to afford the process and wish to be sure of quality results. However this program may not be necessary nor appropriate for a great many people. There are probably millions who suffer the inconvenience of a degree of deafness who can benefit from the modestly priced hearing aids available, from mail order companies for the most part, some of which are surprisingly well made. These people would often be willing to make the relatively small investment to improve their situation, but when confronted with the high cost of the full medical procedure and the usual resulting name brand purchases, would be likely to conclude they can do without.

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Third - In the area of consumer protection as you are aware, there is a requirement that a free trial period be offered, during which the sale can be cancelled and the money refunded. This is a significant protection, and in addition some vendors offer extended trials, and include reasonable warranty periods, often further extendible at a modest cost, with stated repair services after warranty expiration. As for physical risk, it's hard to conjure one from merely trying hearing aids.

Fourth - The mere presence of an alternative has a beneficial effect on the major vendors and manufacturers tending to encourage more affordable pricing, better service, more research, and better product quality. It is even possible that it might create more customers for the first line companies in time as individuals having realized the benefits of enhanced hearing, might decide to upgrade at a later date to maximise the improvements.

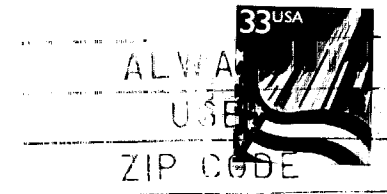
Fifth - Substantial groups of people have religious beliefs which preclude or restrict resort to medical assistance. Are we to require them to violate their tenets on the one hand or to forego readily available help on the other?

In summary, it would appear that there is no need to interfere with freedom of choice in this area.

Sincerely,


Richard C. Snodgrass

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